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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,274	02/01/2001	John S. Kelly	200549USOPCT	8149

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EXAMINER

KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/02/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,274

Applicant(s)

KELLY ET AL.

Examiner

Brian S Kwon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Status of Application

1. Acknowledgement is made of applicant's filing of application SN 09/743/274 as RCE.
2. By the amendment filed April 10, 2002, claims 24 and 25 have been cancelled and claims 15 and 17 have been amended. Claims 15-23 are currently pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abu-Elmagd et al. (AN 1995:242744) in view of Kagayama et al. (EP 073297 A1), and if necessary, further in view of Higa et al. (US 4859782).

The claims read on a method for providing a topical analgesic effect, comprising topically administering to a mammal an effective amount of a macrolide compound of the formula (I). Further limitations include FK 506 as the macrolide compound in claim 16; the mammal is suffering from arthritis in claim 17; 0.001 to 20% (w/w) of the macrolide compound, more specifically 0.01 to 10% (w/w) of the macrolide compound in claims 16-20; in the form of an ointment, gel, lotion, aerosol spray, cream skin plaster or patch in claim 21; the mammal is human in claim 22.

Abu-Elmagd teaches or suggests the oral use of tacrolimus (FK-506) for treating pain associated with severe pyoderma gangrenosum in patient with streaking leukocyte factor disease.

Kagayama teaches or suggests the topical administration of FK 506 (e.g., lotion) for treating rheumatoid arthritis (page 9, lines 1-2), wherein the amount of FK 506 is from 0.01 to 10% w/w (page 5, lines 24-25; Examples 1-6). Kagayama teaches that the topical lotion is excellent in absorption (Table 1).

The teaching of Abu-Elmagd differs from the claimed invention in (i) the topical use of FK 506, (ii) the treatment of pain associated with arthritis, and (iii) the specific concentration of macrolide.

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To incorporate such teaching into the teaching of Abu-Elmagd, would have been obvious in view of Kagayam who teaches or suggests the topical application of FK 506 in the dosage range of 0.1-10% w/w for treating rheumatoid arthritis.

One having ordinary skill in the art would have known in view of Kagayama that the topical application of FK 506 would have excellent absorption, and would provide good therapeutic effects as the oral administration. One having ordinary skill in the art would have expected that the topical administration of FK 506 would be useful in reliving pain associated with pyoderma gangrenosum patient. Furthermore, one having ordinary skill in the art would have expected that “a marked reduction in his pain” in Abu-Elmagd (page 5, column 2, line 13) is due to well-known analgesic property of FK 506. Additionally, one having ordinary skill in the art would have expected that either oral or topical application of FK 506 would be effective in treating arthritis or pain that is associated with arthritis. Therefore, one having ordinary skill in the art would have been motivated to employ FK 506 having analgesic property topically such that topical FK 506 would provide effective and sustained treatment against pain associated with arthritis or pyoderma gangrenosum lesions while minimizing the adverse effects associated with oral FK 506 administration.

Conclusion

4. No Claim is allowed.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703)308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600

A handwritten signature in black ink, appearing to read 'Zohreh Fay', written in a cursive style.